

Energy Control for Research Sterilizer

Overview

Purpose The intended use of this procedure is to describe the method for effectively locking and tagging the multiple hazardous energy sources. Only lock out / tag out trained employees are authorized to perform this work.

Scope This document applies to equipment types as described within this procedure located at Boston Scientific Maple Grove or Plymouth Campuses with the following equipment located in the Research Sterilizer area:

| BSC ID/IQR# | Equipment Description | BSC ID/IQR# | Equipment Description |
|-------------|-----------------------|-------------|-----------------------|
| 90005830 | AAT Controls | 90006155 | Vacuum |
| 90005835 | Damper Controls | 90006159 | Aeration Chamber # 1 |
| 90005883 | Safe Cell 2 | 90006180 | Aeration Chamber # 2 |
| 90005938 | Safe Cell 1 | 90006184 | Scale 1, 100% EO |
| 90005943 | Exhaust Blower | 90006188 | Scale 2, Oxyfume |
| 90005949 | EO Monitor 100% | 90006192 | Recirculation Blower |
| 90006063 | EO Monitor Oxyfume | 90006196 | RO Water |
| 90006086 | Steam Boiler | 90006201 | Clean Steam |
| 90006091 | Sterilizer Controls | 90006205 | Vaporizer |
| 90006095 | Chamber | 90006214 | PLC |
| 90006108 | Booster Pump | 90006220 | WonderWare |
| 90006145 | Heat Exchangers | 90006226 | Panelview |
| 90006149 | Vented Cabinet | | |

Applicable Documents

See the table below for documents referenced in this procedure:

| Document Name | Document Number |
|--|-----------------|
| Lock out / Tag out | 90002763 |
| Research Sterilizer Operation | 90032956 |
| Research Sterilizer Preventive Maintenance | 90042073 |

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Boston Scientific
Energy Control for Research Sterilizer
90953779 Rev/Ver AA

Overview - continued

Equipment & Materials

See the table below for equipment and materials referenced in this procedure:

| Description | Part Number |
|-------------------------------------|-------------|
| Red locks or red banded locks | N/A |
| Red and white striped “Danger” tags | N/A |
| Lock out hasps | N/A |
| Electrical cord plug lock out | N/A |
| Electrical switch lock out | N/A |
| Ball valve lock out | N/A |
| Butterfly valve lock out | N/A |

Definitions

The following terms are used in this procedure:

| Term | Definition |
|-------------------------|---|
| Energy isolating device | A device that physically prevents the release or transmission of energy. |
| Hazardous energy | Energy, which if not controlled, could cause injury or death including but not limited to: electrical, chemical, mechanical, hydraulic/pneumatic, or thermal. |
| Lockout device | A device that utilizes a positive means to hold an energy isolating device in a safe position. |
| Lock out hasp | Used to affix multiple locks to an energy isolating device. |

Procedure


Energy Control Procedure



Complete the following steps for complete de-energization of this equipment.


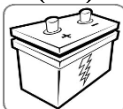
| Step | Action |
|------|---|
| 1 | Notify all affected personnel and confirm personnel are clear of hazards. |
| 2 | Turn off power at disconnect points listed below. |
| 3 | Lock out each energy control point listed below in the off position by affixing an approved lock and tag to a lockout device. |
| 4 | Dissipate/disconnect any stored energy. |
| 5 | Attempt to re-start machinery or re-energize equipment through normal means. |
| 6 | Perform required work. |


Temporary Removal

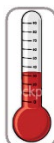
Temporary removal of lock out / tag out devices is allowed for testing or positioning of machines or equipment provided that all steps for application and removal of lock out / tag out devices are followed and that the machinery or equipment is returned to the original, de-energized condition prior to continuing work.

| Energy Source | Location to Lock Out | Method to Lock Out | How to Confirm Effective Lock Out | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|--|--|-------------|----------|---------|----------|--------------|----------|--------|----------|----------------------|----------|----------------------|----------|----------------------|---|-------------|-------------|----------|-----------------|----------|--------------------|----------|---------------------|----------|---------|----------|----------------|----------|------------------|----------|------------------|----------|-----|----------|------------|
| <div>Electrical (E)</div> <div></div> | <p>Sterilizer main electrical disconnect is located in control room on door to enclosure #1. (E-1)</p> <p>This switch controls 3-phase electric supply to pumps and motors for the following components of the Research Sterilizer system:</p> | <p>Turn switch to “off” position and use switch lock out device or individual circuit breaker may be locked off.</p> <p>NOTE: 24V DC service is maintained by the UPS (SE-1) for the PLC, Compressed Air Control and sensors in the following components of the Research Sterilizer system.</p> | <p>Attempt to re-start – no action should occur.</p> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | <table><tr><th>BSC ID/IQR#</th><th>Description</th></tr><tr><td>90006095</td><td>Chamber</td></tr><tr><td>90006108</td><td>Booster Pump</td></tr><tr><td>90006155</td><td>Vacuum</td></tr><tr><td>90006159</td><td>Aeration Chamber # 1</td></tr><tr><td>90006180</td><td>Aeration Chamber # 2</td></tr><tr><td>90006192</td><td>Recirculation Blower</td></tr></table> | BSC ID/IQR# | | Description | 90006095 | Chamber | 90006108 | Booster Pump | 90006155 | Vacuum | 90006159 | Aeration Chamber # 1 | 90006180 | Aeration Chamber # 2 | 90006192 | Recirculation Blower | <table><tr><th>BSC ID/IQR#</th><th>Description</th></tr><tr><td>90005949</td><td>EO Monitor 100%</td></tr><tr><td>90006063</td><td>EO Monitor Oxyfume</td></tr><tr><td>90006091</td><td>Sterilizer Controls</td></tr><tr><td>90006095</td><td>Chamber</td></tr><tr><td>90006149</td><td>Vented Cabinet</td></tr><tr><td>90006184</td><td>Scale 1, 100% EO</td></tr><tr><td>90006188</td><td>Scale 2, Oxyfume</td></tr><tr><td>90006214</td><td>PLC</td></tr><tr><td>90006220</td><td>WonderWare</td></tr><tr><td>90006226</td><td>Panelview</td></tr></table> | BSC ID/IQR# | Description | 90005949 | EO Monitor 100% | 90006063 | EO Monitor Oxyfume | 90006091 | Sterilizer Controls | 90006095 | Chamber | 90006149 | Vented Cabinet | 90006184 | Scale 1, 100% EO | 90006188 | Scale 2, Oxyfume | 90006214 | PLC | 90006220 | WonderWare |
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| 90006095 | Chamber | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 90006108 | Booster Pump | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 90006155 | Vacuum | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 90006159 | Aeration Chamber # 1 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 90006180 | Aeration Chamber # 2 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 90006192 | Recirculation Blower | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| BSC ID/IQR# | Description | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 90005949 | EO Monitor 100% | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 90006063 | EO Monitor Oxyfume | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 90006091 | Sterilizer Controls | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 90006095 | Chamber | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 90006149 | Vented Cabinet | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 90006184 | Scale 1, 100% EO | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 90006188 | Scale 2, Oxyfume | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 90006214 | PLC | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 90006220 | WonderWare | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 90006226 | Panelview | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

| Energy Source (Cont'd) | Location to Lock Out | Method to Lock Out | How to Confirm Effective Lock Out | | | | | | | | | | | | | | |
|--|--|--------------------|--------------------------------------|----------|--------------|----------|-----------------|----------|-------------|----------|-------------|----------|----------------|----------|-----------------|---|---|
| <div>Electrical (E)</div> <div></div> | <div>Emissions main disconnect is located in control room on emissions control panel. (E-2)</div> <div>This controls the following components of the emissions control system including the roof-top exhaust.</div> <table><tr><th>BSC ID/IQR#</th><th>Description</th></tr><tr><td>90005830</td><td>AAT Controls</td></tr><tr><td>90005835</td><td>Damper Controls</td></tr><tr><td>90005883</td><td>Safe Cell 2</td></tr><tr><td>90005938</td><td>Safe Cell 1</td></tr><tr><td>90005943</td><td>Exhaust Blower</td></tr><tr><td>90006210</td><td>Water Processor</td></tr></table> | BSC ID/IQR# | Description | 90005830 | AAT Controls | 90005835 | Damper Controls | 90005883 | Safe Cell 2 | 90005938 | Safe Cell 1 | 90005943 | Exhaust Blower | 90006210 | Water Processor | Turn switch to “off” position and use switch lock out device or individual circuit breaker may be locked off. | Attempt to re-start – no action should occur. |
| BSC ID/IQR# | Description | | | | | | | | | | | | | | | | |
| 90005830 | AAT Controls | | | | | | | | | | | | | | | | |
| 90005835 | Damper Controls | | | | | | | | | | | | | | | | |
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| 90005938 | Safe Cell 1 | | | | | | | | | | | | | | | | |
| 90005943 | Exhaust Blower | | | | | | | | | | | | | | | | |
| 90006210 | Water Processor | | | | | | | | | | | | | | | | |
| <div>Mechanical (M)</div> <div></div> | N/A | N/A | N/A | | | | | | | | | | | | | | |

| Energy Source (Cont'd) | Location to Lock Out | Method to Lock Out | How to Confirm Effective Lock Out | | | | | | | | | | | | | | | | | | | | | | |
|--|---|--|--|----------|-----------------|----------|--------------------|----------|---------------------|----------|---------|----------|----------------|----------|------------------|----------|------------------|----------|-----|----------|------------|----------|-----------|--|--|
| Chemical (C)  | Ethylene Oxide resides within the EO cabinet. (C-1) | Tank valve can be closed and secured with a clamshell lock. Caution. EO will remain in lines to main control valves. | N/A | | | | | | | | | | | | | | | | | | | | | | |
| | Sulfuric acid resides in safe-cell #1 to the left of the sterilizer on the floor. (C-2) | Acid circulation is ceased by isolating main sterilizer electrical disconnect. Acid can be isolated by closing ball valve and applying ball valve lock out. | Attempt to re-start – no action should occur.. | | | | | | | | | | | | | | | | | | | | | | |
| Stored Energy (SE)  | UPS for 24V DC service is located in control room on top of enclosure #1. (SE-1) This controls 24V DC service for the PLC, Compressed Air Control and sensors in the following components of the Research Sterilizer system. | UPS power cord can be removed and plug lock applied | Attempt to re-start – no action should occur. | | | | | | | | | | | | | | | | | | | | | | |
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| | 90006184 | Scale 1, 100% EO | | | | | | | | | | | | | | | | | | | | | | | |
| | 90006188 | Scale 2, Oxyfume | | | | | | | | | | | | | | | | | | | | | | | |
| | 90006214 | PLC | | | | | | | | | | | | | | | | | | | | | | | |
| | 90006220 | WonderWare | | | | | | | | | | | | | | | | | | | | | | | |
| 90006226 | Panelview | | | | | | | | | | | | | | | | | | | | | | | | |
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| Energy Source (Cont'd) | Location to Lock Out | Method to Lock Out | How to Confirm Effective Lock Out |
|--|--|---|---|
| Pneumatic / Hydraulic (PH)  | Main compressed air is located in control room above enclosure #4. (PH-1) | Pressure regulator is closed and clamshell lock applied. Lines can be bled if necessary | No pressure present on gage. |
| | Compressed air for emissions control system is located in control room above emission enclosure (PH-2) | | |
| | Main nitrogen valve is located in sterilizer room above door to gas storage area. (PH-3) | Ball valve is closed and ball valve lock applied. Lines can be bled if necessary. | No pressure present on gage. |
| | Gas chromatograph tanks are located in boiler room by RO mini-loop (PH-4) | Close tank valves and apply clamshell lock. | |
| | RO Water shutoff is located on the wall behind the RO system. (PH-5) | Ball valve is closed and ball valve lock applied. | N/A |
| | RO electrical disconnect is located on the wall behind the RO system. (PH-6) | Turn switch to "off" position and use switch lock out device. | Attempt to re-start – no action should occur. |
| | Chiller heat exchange fluid shutoff is located on the wall at the rear of the sterilization chamber. (PH-7) | Ball valve is closed and ball valve lock applied. | N/A |
| | Main soft water supply shutoff (serving everything except the boiler) is located near the ceiling of the sterilizer room. (PH-8) | | |
| | Boiler soft water supply shutoff is located near the ceiling of the sterilizer room. (PH-9) | | |

| Energy Source (Cont'd) | Location to Lock Out | Method to Lock Out | How to Confirm Effective Lock Out | | | | | | | | | | | | | | | | |
|--|--|----------------------|--------------------------------------|----------|--------------|----------|----------|----------|-----------------|----------|----------------------|----------|----------------------|----------|-------------|----------|-----------|---|--|
| <div>Thermal (T)</div> <div></div> | <p>Main boiler is located in boiler room to the side of the sterilizer. It provides steam to:</p> <table><tr><th>BSC ID/IQR#</th><th>Description</th></tr><tr><td>90006086</td><td>Steam Boiler</td></tr><tr><td>90006095</td><td>Chamber*</td></tr><tr><td>90006145</td><td>Heat Exchangers</td></tr><tr><td>90006159</td><td>Aeration Chamber # 1</td></tr><tr><td>90006180</td><td>Aeration Chamber # 2</td></tr><tr><td>90006201</td><td>Clean Steam</td></tr><tr><td>90006205</td><td>Vaporizer</td></tr></table> | BSC ID/IQR# | Description | 90006086 | Steam Boiler | 90006095 | Chamber* | 90006145 | Heat Exchangers | 90006159 | Aeration Chamber # 1 | 90006180 | Aeration Chamber # 2 | 90006201 | Clean Steam | 90006205 | Vaporizer | <p>Turn switch to “off” position and use switch lock out device.</p> <p>Close main liquid valve and secure with clamshell lock.</p> | <p>Attempt to re-start – no action should occur.</p> |
| | BSC ID/IQR# | Description | | | | | | | | | | | | | | | | | |
| | 90006086 | Steam Boiler | | | | | | | | | | | | | | | | | |
| | 90006095 | Chamber* | | | | | | | | | | | | | | | | | |
| | 90006145 | Heat Exchangers | | | | | | | | | | | | | | | | | |
| | 90006159 | Aeration Chamber # 1 | | | | | | | | | | | | | | | | | |
| | 90006180 | Aeration Chamber # 2 | | | | | | | | | | | | | | | | | |
| | 90006201 | Clean Steam | | | | | | | | | | | | | | | | | |
| | 90006205 | Vaporizer | | | | | | | | | | | | | | | | | |
| | <p>Main electrical disconnect is located on the wall to the left of the boiler. (T-1)</p> <p>Main liquid valve is located on top of boiler. (T-2)</p> <p>Condensate return pump electrical disconnect is on the wall to behind the condensate pump and next to the RO system. (T-3)</p> <p>*NOTE: Steam for the chamber is produced by 90006201 which uses 90006086 as its heat source. Shutting down 90006086 will stop clean steam production.</p> | | | | | | | | | | | | | | | | | | |

Energy Control Location Photos



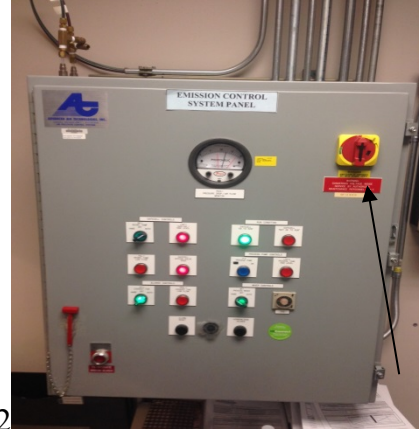
C-1



C-2



E-1



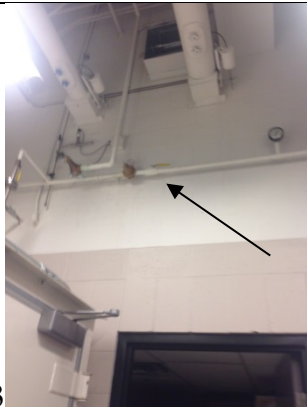
E-2



PH-1



PH-2



PH-3



PH-4

Energy Control Location Photos (cont'd)

PH-5



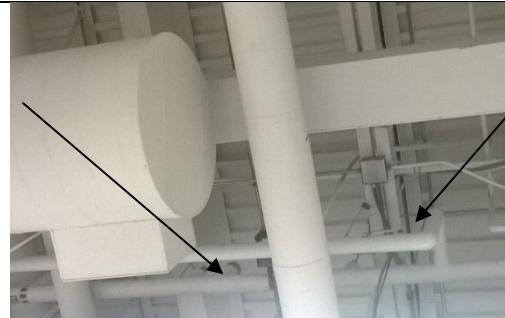
PH-6



PH-7



PH-8 (left) and PH-9 (right)



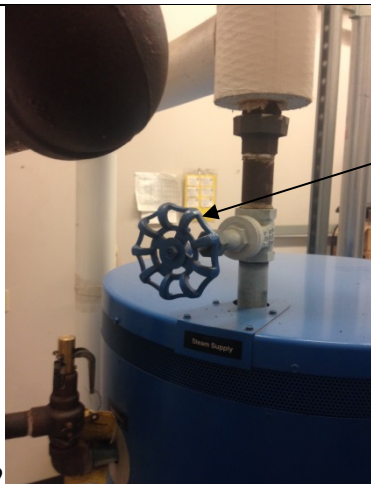
SE-1



T-1



T-2



T-3



**Procedure to
Return Tool to
Operation**

Complete the following steps for complete re-energization of this equipment.

| Step | Action |
|------|--|
| 1 | Inspect the work area to ensure that all non-essential items, tools, or employees have been removed from the area. |
| 2 | Unlock and remove any blocking devices. |
| 3 | Reposition any safety guards. |
| 4 | Warn workers to stay clear of area. |
| 5 | Remove all locks and tags from energy control points. |
| 6 | Confirm that the area is clear of personnel. |
| 7 | Re-start the equipment. |
| 8 | Notify all affected personnel that the lockout has been cleared. |

**Normal
Operation
Adjustments**

Minor tool changes and adjustments, and other minor servicing activities, which take place during normal production operations, do not require lock out if they are routine, repetitive, and integral to the use of the equipment for production, provided that the work is performed using alternative measures which provide effective protection. The following apply to this procedure:

| Operation | Alternate Method of Protection |
|------------------------|----------------------------------|
| Preventive Maintenance | Follow instructions in 90042073. |
| EO Cylinder Change | Follow instructions in 90032956. |